UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	MDL No. 1:13-MD-2428-DPW
	REDACTED FILING
This Document Relates to:	
Charles Cameron, Individually and as Wrongful Death Beneficiary of Charles Cameron, Sr., Case No. 1:13-cv-12446-DPW;	
Daniel Carter, Individually and on Behalf of the Wrongful Death Beneficiaries of Anniece Carter, Case No. 1:13-cv-12459-DPW;	
Geraldine Dillingham, as Next of Kin and Personal Representative of Estate of Ronnie Dillingham, Case No. 1:15-cv-12796-DPW;	
Alex Kazos, as Next of Kin and Personal Representative of Estate of Nick Kazos, Case No. 1:15-cv-12376-DPW;	
Kathleen Palmaccio, as Next of Kin and Personal Representative of Estate of John Palmaccio, Case No. 1:15-cv-12474-DPW;	
Sharon Randall, as Next of Kin and Personal Representative of Estate of Winfitch Randall, Case No. 1:15-cv-12735-DPW;	
Amy Riben, Wife, and Max Riben, Husband, And Their Marital Community, Case No. 1:15-cv-11134-DPW;	
Tamika Smith, as Next of Kin and Personal Representative of Estate of Cynthia Reed, Case No. 1:15-cv-12768-DPW;	
Sophia Walker, Individually and on Behalf of the Wrongful Death Beneficiaries of Hattie Myles, Case No. 1:13-cv-12487-DPW;	

Angelos Zachery, et al., Individually and as Executor of the Estate of Nellie Fredrick McClendon, Case No. 1:14-cv-13150-DPW	)

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF FMCNA'S MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF OPT-OUT PLAINTIFFS INVOLVING NATURALYTE

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56.1, Defendants, Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. ("FMCNA") submit this statement of undisputed material facts in support of their motion for summary judgment on the claims of all opt-out plaintiffs who lack evidence that the acid concentrate used in the last dialysis treatment prior to the alleged injury was GranuFlo®, rather than NaturaLyte®, including: Geraldine Dillingham (Ronnie Dillingham); Alex Kazos (Nick Kazos); Kathleen Palmaccio (John Palmaccio); Sharon Randall (Winfitch Randall); Tamika Smith (Cynthia Reed); Max Riben (Amy Riben); Daniel Carter (Anniece Carter); Angelos Zachery (Nellie Fredrick McClendon); Charles Cameron (Charles Cameron, Sr.); and Sophia Walker (Hattie Myles).

Facts Applicable to All Plaintiffs

1. NaturaLyte® is a liquid acid concentrate that contains various electrolytes and 4 milliequivalents per liter (mEq/L) of acetic acid. When combined with a bicarbonate concentrate and water, NaturaLyte® provides 4 mEq/L of acetate to the dialysis solution. 2d Amended Master Complaint ¶ 97 (Doc. 1232).

2. GranuFlo® is a dry powder acid concentrate that contains various electrolytes, 4 mEq/L of sodium acetate and 4 mEq/L of acetic acid (that together are present in the form of

sodium diacetate). When combined with a bicarbonate concentrate and water, GranuFlo® provides 8 mEq/L of acetate to the dialysis solution. 2d Amended Master Complaint ¶ 98.

3. The U.S. Food and Drug Administration (FDA) cleared NaturaLyte® for marketing in 1981. Ex. 1, FMC-MDL-00083413-50.

4. FDA cleared GranuFlo® for marketing in 1991. Ex. 2, FMC-MDL-00055107-211.

5. FDA cleared NaturaLyte® and GranuFlo® pursuant to Section 510(k) of the Medical Device Amendments of 1976, which allows manufacturers to market products that are "substantially equivalent" to medical devices that were already on the market when the MDA took effect. Ex. 1-2.

6. In the years since NaturaLyte® was cleared for sale, every manufacturer of acid concentrates for hemodialysis has offered a liquid product with 4 mEq/L of acetate, and they continue to do so. Ex. 3, RenalPure, Renasol, and Diasol.

7. The labels for other liquid acid concentrate products with 4 mEq/L of acetate identify the acetate contents in the same manner that the NaturaLyte® label identifies its acetate contents. Ex. 4 (competitor labels), 5 (additional competitor labels), 6 (sample NaturaLyte® label). George Samaras, the industry standards expert witness whom the plaintiff called at trial in Florella Dial v. Fresenius Medical Care Holdings, Inc., et al., D. Mass. Case No. 1:14-cv-11101, agreed that the format of the NaturaLyte® label is just like that of every other industry participant for acid concentrates that contain 4 mEq/L of acetate. Ex. 7, Dial Trial Tr., 8-122-123.

8.

9. NaturaLyte® has been used in clinical settings since the early 1980s and has been used in hundreds of millions of hemodialysis treatments. Ex. 8, Dial Trial Tr., 11-91-92; see also Ex. 7, Dial Trial Tr., 8-120-121.

10. This MDL was established by Order of the Judicial Panel on Multidistrict Litigation, dated March 29, 2013, to centralize litigation involving "injuries or deaths allegedly caused by use of GranuFlo Acid Concentrate (GranuFlo) and NaturaLyte Liquid Acid Concentrate (NaturaLyte) during hemodialysis." MDL Docket 2.

11. Plaintiffs' Master Complaint submitted to the Court on December 20, 2013, alleged, at paragraph 1, "The products that are the subject of the litigation are any dry acid concentrate, whether it be labeled by the Defendants as 'GranuFlo' or 'NaturaLyte' or both, yielding a concentration of acetate greater than 4 meq/L when put into solution for use in dialysis, by including sodium diacetate in the product's formulation. These products are described hereafter collectively as 'NaturaLyte and/or GranuFlo'." MDL Docket 467-1 at ¶ 1.

12. Plaintiffs' Master Complaint submitted to the Court on December 20, 2013, alleged, at paragraph 97, "GranuFlo and/or NaturaLyte have been on the market for many years and are unique in the dialysis treatment world in that they contain sodium diacetate. Through this formulation, GranuFlo and/or NaturaLyte increase the amount of acetate in dialysate (the fluid and solutes in a dialysis process that flow through the dialyzer machine) compared to more traditional formulations made with acetic acid." MDL Docket 467-1 at ¶ 97.

13. Plaintiffs' Master Complaint submitted to the Court on December 20, 2013, alleged, at paragraph 105, "All acid concentrates (liquid or dry) contain acid. Liquid products contain acetate, whereas NaturaLyte and/or GranuFlo contain sodium diacetate." MDL Docket 467-1 at ¶ 105.

14. Plaintiffs' Master Complaint submitted to the Court on December 20, 2013, alleged, at paragraph 107, "NaturaLyte and/or GranuFlo contain sodium diacetate (two acetates), whereas other products contain only acetic acid with one acetate. Once in the body, acetate is converted by the patient's liver into bicarbonate. Because NaturaLyte and/or GranuFlo results in two acetate molecules, conversion by the liver results in *two molecules of bicarbonate*. Thus, the net effect of using a dialysate that contains diacetate is that the patient is exposed to an unanticipated amount of bicarbonate and consequently an unanticipated amount of total buffer that exceeds what was intended and ordered by the physician attending to the patient. The conversion of diacetate in the liver to two molecules of bicarbonate results in a higher total buffer than ordered by the physician." MDL Docket 467-1 at ¶ 107.

15. At one time, GranuFlo®, FMCNA's dry acid concentrate product with 8 mEq/L of acetate, was sold under the trade name "NaturaLyte GranuFlo." Ex. 9.

16. On August 22, 2014, plaintiffs filed a motion for leave to file their Amended Master Complaint. MDL Docket 725. In that motion, plaintiffs stated, "With the number of filings growing in the last several months, the PEC recently learned that a substantial number of actions in this MDL – perhaps 40% – involve NaturaLyte" rather than GranuFlo®. Id. at p. 1. The motion further stated, "The PEC seeks leave to amend the Master Complaint to clarify that the MDL and Master Complaint includes claims regarding both GranuFlo and NaturaLyte." Id. The Court granted plaintiffs' motion on October 10, 2014. MDL Docket 776.

17. On June 2, 2015, Plaintiffs filed a motion for leave to file their Second Amended Master Complaint. MDL Docket 1178. In their motion, in reference to their prior amendment of the Master Complaint, Plaintiffs again stated, "As filings continued, the parties began to

understand that many individual cases in the MDL involved the related dialysate NaturaLyte rather than GranuFlo." Id. at p. 2.

18. Plaintiffs' Second Amended Master Complaint alleges, at paragraph 110, that "the net effect of the conversion of acetic acid contained in NaturaLyte or sodium diacetate contained in GranuFlo is that the patient is exposed to an unanticipated amount of bicarbonate and consequently an unanticipated amount of total buffer that exceeds what was prescribed by the physician attending to the patient." MDL Docket 1232 at ¶ 110.

19. Plaintiffs retained Steven C. Borkan, MD, as an expert witness on general and specific causation in this litigation.

20. Dr. Borkan is a professor at Boston University and also maintains an active clinical nephrology practice in facilities affiliated with DaVita. Ex. 11, June 2, 2015 Deposition of Steven Borkan, MD, at 10:22 – 11:9; see also Ex. 10, p. 2.

21. Dr. Borkan testified as an expert on behalf of the plaintiffs in a lawsuit pending against DaVita Healthcare Partners, Inc. ("DaVita") in the U.S. District Court for the District of Colorado, captioned Donald Thornton, individually and as personal representative of the Estate of Jean Thornton, and on behalf of all others similarly situated, v. DaVita Healthcare Partners, Inc., Case No. 1:13-cv-00573-RBJ-KMT. At his deposition on October 10, 2014, in that action, he testified, in part:

> Q. Now, Paragraph 14 -- just before Paragraph 14, there's a heading in bold that's there that says "NaturaLyte and/or GranuFlo that contain excess acetate increase death risk." Do you see where I'm referring?
>
> A. (Witness nodded.)
>
> Q. You have to answer verbally.
>
> A. Yes, I do.
>
> Q. That heading, is there NaturaLyte or GranuFlo, in your opinion, that does not contain excess acetate, as you've described it?
>
> A. Yes. That would be the solutions that contain 4 mEq/L of acetate, rather than eight.

Ex. 12, October 10, 2014 Deposition of Steven Borkan, MD, in Thornton v. DaVita, at p. 149 ("Borkan Deposition in Thornton").

22. At his October 10, 2014, deposition in Thornton, Dr. Borkan further testified, in part:

> Q. In Paragraph 9, you have a reference to errors in the chemical composition of dialysate solution. And are the errors that you're referring to there the use of acetate in the form of sodium diacetate in the GranuFlo product or something else?

A. No. I am referring to the increase in acetate caused by exposure to the GranuFlo or NaturaLyte solutions that were made with 8 milliequivalents of acetate equivalent.

Q. So if there was another acid concentrate product that contained acetate in the level that converted to 4 milliequivalents of bicarbonate, would that have an error in its chemical composition, as well, or not because it's not to the level of eight that you've been talking about?

A. The latter. Since it's not to the level of eight, and, therefore, would not push the patient's bicarbonate into the 40s, post dialysis. It would not result in as severe perturbations in calcium, potassium, contractility and the susceptibility to hypoxemia.

Ex. 12, Borkan Deposition in Thornton, at pp. 136-137.

23. At his October 10, 2014, deposition in Thornton, Dr. Borkan further testified, in part:

Q. You reference in Paragraph 19 "incorrectly manufactured" NaturaLyte or GranuFlo solutions. And your reference to "incorrectly manufactured," does that mean containing a level of acetate beyond the 4 milliequivalents that we've talked about?

A. That's correct.

Ex. 12, Borkan Deposition in Thornton, at p. 157.

24. At his October 10, 2014, deposition in Thornton, Dr. Borkan further testified, in part:

Q. Are you aware . . . whether any of the patients for whom you oversee the dialysis treatment now, during the four and a half or five months that you're in clinical services, are being treated with GranuFlo or NaturaLyte?

A. Yes. I am aware that my DaVita unit . . . uses a NaturaLyte product.

Q. Okay. And have you done anything to advise your patients of that fact?

A. I do not believe that advising them is necessary, because the solutions contain an amount of acetate that is acceptable.

Q. Which is what, just so that I'm clear? Is that 4 milliequivalents or less? Is that –

A. Yes. That's correct.

Ex. 12, Borkan Deposition in Thornton, at pp. 161-162.

25. At the class certification and Daubert hearing in Thornton, Dr. Borkan testified, in part:

> Q. Sure. I think you just said . . . that treating a dialysis patient with a dialysate containing acetate at a level greater than 4 milliequivalents per liter falls below the medical standard of care; is that fair?
>
> A. That's correct.
>
> Q. So, is it the case, then, that treating a patient with a dialysate containing acetate at a level of 4 milliequivalents or below would not fall below the standard of care?
>
> A. In general, it turns out that that is the default or average dialysate that patients are exposed to. That's the background or baseline. And it's my understanding that there has to be some small acid component in the electrolyte solution of dialysis machines in order to maintain the proper balance of electrolytes.

Ex. 13, Transcript of Class Certification and Daubert Hearing in Thornton, at p. 280.

26. At the class certification and Daubert hearing in Thornton, Dr. Borkan further testified, in part:

> Q. And the level -- I think you said it a few minutes ago, and I think you said it yesterday -- the typical amount of acetate contained in a conventional bicarbonate-based dialysate is around 4 milliequivalents?
>
> A. That's correct.
>
> Q. So that when you're talking about . . . excess acetate going into a patient's body and then converting into what you call excess bicarbonate, you're talking about the additional 4 milliequivalents that GranuFlo has of acetate beyond the typical other dialysate that contains lower levels?
>
> A. Yes, that's correct.

Ex. 13, Transcript of Class Certification and Daubert Hearing in Thornton, at pp. 282-83.

27.

28.

29.

30. At the trial held in Florella Dial v. Fresenius Medical Care Holdings, Inc., et al., D. Mass. Case No. 1:14-cv-11101, in February 2017, the plaintiff called Dr. Borkan as a general and case-specific nephrology expert witness. During his trial testimony in Dial, Dr. Borkan acknowledged that acetic acid (which becomes acetate in the dialysate solution) is needed to prevent other electrolytes such as calcium from precipitating out of the acid concentrate. Ex. 15, Dial Trial Tr., 7-13.

31. During his trial testimony in Dial, Dr. Borkan admitted that NaturaLyte® has been on the market since before he became a nephrologist and has been sold with 4 mEq/L of acetate and used in dialysis treatments since the early 1980s. Ex. 15, Dial Trial Tr., 7-13.

32. During his trial testimony in Dial, Dr. Borkan reaffirmed his prior admissions that 4 mEq/L of acetate is an "average," "background," and "baseline" amount for an acid concentrate. Ex. 15, Dial Trial Tr., 7-15-16.

33. During his trial testimony in Dial, Dr. Borkan acknowledged that acid concentrates with 4 mEq/L of acetate, such as NaturaLyte®, do not contain "excess acetate." Ex.

15, Dial Trial Tr., 7-18-19.

34. During his trial testimony in Dial, Dr. Borkan confirmed that he has dialyzed "many thousands" of his own patients with NaturaLyte®, is still using it today, and does not advise patients of that fact. Ex. 15, Dial Trial Tr., 7-16-21.

35.

36.

37. After a short period of deliberations, the jury in Dial returned a verdict for FMCNA after concluding that NaturaLyte® was not the proximate cause of the decedent's death. The case was decided on medical causation, and the jury did not reach questions regarding the adequacy of FMCNA's warnings regarding NaturaLyte®, as reflected in the verdict slip. Ex. 18.

38. Sushrut Waikar, MD, one of Plaintiffs' retained experts on general causation and the Director of Ambulatory Services in the Renal Division at Brigham and Women's Hospital, testified at his deposition on May 26, 2015, that the dialysis unit at Brigham and Women's uses a dialysate product that contains 4 mEq/L of acetate. Ex. 19, May 26, 2015 Deposition of Sushrut Waikar, MD, at 46:4-22. Dr. Waikar further testified that he has never expressed to his patients the opinion that 4 mEq/L of acetate is unsafe. Id.

39. In his December 3, 2015 testimony at trial in the Ogburn matter in the Massachusetts consolidated proceedings, Dr. Waikar testified in part as follows:

> Q. At Brigham and Women's, is the average prescription for bicarbonate 35 milliequivalents per liter?
>
> A. It is.
>
> Q. And for acetate – I'm sorry, for the acid concentrate that is used at Brigham and Women's, is there 4 acetate in it?
>
> A. There is, yes.
>
> Q. Now, do you warn your patients that there's 4 acetate in the dialysate that might metabolize into bicarbonate?
>
> A. Can you repeat? Do I warn –
>
> Q. Sure. Do you warn them? You've told us yesterday and today that acetate is bad, you don't want to expose your patients to acetate. But it sounds like you're exposing your patients to acetate, is that right?
>
> A. The answer is yes, we do use acetate in the dialysate.
>
> Q. And do you tell them that they're being exposed to acetate, the patients?
>
> A. Generally, no.

Ex. 20, Transcript of Trial in In re Consolidated Fresenius Cases, MICV2013-03400-O, at 1018:15 – 1019:13.

40. David Goldfarb, MD, another expert retained by plaintiffs, testified that the clinic where he treats his hemodialysis patients uses an acid concentrate that contains 4 mEq/L of acetate. Ex. 21, June 19, 2015 Deposition of David Goldfarb, MD, at 80:5 – 81:13, 161:9-13, 162:22 – 164:8.

41. Derek Fine, MD, another expert retained by Plaintiffs, testified that his inpatient dialysis patients and chronic dialysis patients are treated with NaturaLyte®. Ex. 22, June 3, 2015 Deposition of Derek Fine, MD ("Fine Dep."), at 136:14-24.

42. Dr. Fine further testified that his patients, who are dialyzed with NaturaLyte®, generally "aren't alkalotic." Ex. 22, Fine Dep., p. 70-71, 136, 170.

43. Paul Miller, MD, the nephrologist who "leaked" the November 4, 2011 memorandum authored by Dr. Raymond Hakim to FDA as alleged in paragraphs 211-213 of the Second Amended Master Complaint (MDL Docket 1178-1), testified that he has used NaturaLyte® in treating his patients and was able to use it in a safe and effective way. Ex. 23, June 24, 2015 Deposition of Paul E. Miller, MD, at 109:14 – 113:2. Dr. Miller testified as follows, in part:

> Q. So my question to you, Doctor, is, having used NaturaLyte, and you do understand that it only has 4 acetate in it, do you believe that NaturaLyte is a fine product to use, if a doctor wanted to?
>
> A. Yes.
>
> Q. And when you used NaturaLyte in your clinics for that period of time between the Gambro dialysate and the GranuFlo, were you able to safely and effectively use it with your patients?
>
> A. Yes.
>
> Q. And by "it" – let me re-ask the question. I did one of the things I try to avoid, okay? When you used NaturaLyte for that period of time prior to using GranuFlo, did you believe that you were able to use NaturaLyte in a safe and effective way to care for your patients?
>
> A. Yes.
>
> ***
>
> Q. And do you have any criticism of a physician today who uses NaturaLyte in his or her dialysis practice?
>
> A. No.

Id. at 109:14 – 110:6, 112:24 – 113:2.

44. Dr. Miller was deposed again on January 19, 2016. During that deposition, Dr. Miller confirmed that he filed litigation against FMCNA in Louisiana under the False Claims Act

in 2012 based on his allegations concerning GranuFlo®, and one of his reasons for doing so was because he hoped to get something out of it monetarily. Ex. 24, January 19, 2016 Deposition of Paul E. Miller, MD, pp. 362-386.

45. During his January 19, 2016, deposition, Dr. Miller agreed that NaturaLyte® is "a fine product" and contains the "standard amount" of acetate, and he testified that it "is a good product to use" to treat dialysis patients. Ex. 24, at pp. 386-387.

46.

47. The Third Edition of the Handbook Of Dialysis provides, in part:

> To circumvent the problem of calcium and magnesium precipitation, a bicarbonate-based dialysate generating system utilizes two concentrate components, a "bicarbonate" component and an "acid" component, the latter containing a small amount of lactic, acetic or citric acid plus sodium, chloride, potassium (if needed), dextrose (optional), and all of the calcium and magnesium. Specially designed dialysis machines mix the two components simultaneously with purified water to make the product dialysis solution. During mixing, the small amount (***usually 4 mM***) of organic acid in the "acid" component reacts with an equimolar amount of bicarbonate in the "bicarbonate" component to generate carbon dioxide. The carbon dioxide which is generated forms carbonic acid, which lowers the pH of the final bicarbonate-containing solution to approximately 7.0 – 7.4.

Ex. 27, Daugirdas, Handbook Of Dialysis, (3d ed. 2001) at p. 59-60 (emphasis added).

Facts Applicable to Plaintiff Dillingham

48.

49.

Facts Applicable to Plaintiff Kazos

50.

51.

52.

Facts Applicable to Plaintiff Palmaccio

53.

54.

55.

56.

Facts Applicable to Plaintiff Randall

57.

58.

59.

60.

Facts Applicable to Plaintiff Smith (Decedent Reed)

61.

62.

Facts Applicable to Plaintiff Riben

63.

64.

65.

66.

Facts Applicable to Plaintiff Carter

67.

68.

69.

70.

71.

Facts Applicable to Plaintiff Zachery (Decedent McClendon)

72.

73.

74.

75.

76.

Facts Applicable to Plaintiff Cameron

77.

78.

79.

Facts Applicable to Plaintiff Walker (Decedent Myles)

80.

81.

82.

83.

Dated: August 23, 2017

Respectfully submitted,

/s/ James F. Bennett

James F. Bennett
Megan S. Heinsz
DOWD BENNETT LLP
773 Forsyth Blvd., Suite 1900
St. Louis, MO 63105
(314) 889-7300
(314) 889-7302 (fax)
jbennett@dowdbennett.com
mheinsz@dowdbennett.com

William H. Kettlewell (BBO # 270320)
Maria R. Durant (BBO # 558906)
Sara E. Silva (BBO # 645293)
COLLORA LLP
100 High Street, 20th Floor
Boston, MA 02110
(617) 371-1000
(617) 371-1037 (fax)
wkettlewell@collorallp.com
mdurant@collorallp.com
ssilva@collorallp.com

Leigh Anne Hodge
BRADLEY ARANT BOULT CUMMINGS LLP
One Federal Place
1819 Fifth Avenue North Birmingham,
AL 35203
(205) 521-8000
(205) 521-8800 (fax)
lhodge@babc.com

Juanita Brooks
FISH & RICHARDSON
12390 El Camino Real
San Diego, CA 92130
(858) 678-5070
(858) 678-5099 (fax)
brooks@fr.com

Counsel for FMCNA

CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on Plaintiffs' counsel by e-mail on August 23, 2017, to:

mollyb@hbsslaw.com

matt@sill-law.com

Orray1@bellsouth.net

dunbarwatt@gmail.com

/s/ James F. Bennett